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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,503	04/03/2000	Gregory N. Nordgren	2408.3775US	4654

7590 04/01/2004
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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

13

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,503

Applicant(s)

NORDGREN, GREGORY N.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-39 and 41-52 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 8-10, 13, 15-22, 27, 28, 32, 33, 41, 44, 47 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6.12.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-5,7,11,12,23-26,29-31,34-39,42,43,45,46,48,49,51 and 52.

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DETAILED ACTION

Election/Restrictions

Applicant's election of Species Q, figures 44-46 and corresponding claims 1, 6, 8-11, 13-22, 27-28, 32-33, 41, 44, 47 and 50 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2-5, 7, 12, 23-26, 29-31, 34-39, 42-43, 45-46, 48-49 and 51-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Additionally, claim 11 has also been withdrawn from further consideration as being drawn to a nonelected invention. Claim 11 recites that the thickness of the terminal end is "nonuniform." Figures 44-46 and the specification relating to figures 44-46 do not indicate this nonuniformity. However, the embodiments of figures 15 and 17-18 do show a nonuniform thickness of the terminal end. Therefore, this claim does not read on the elected invention (Figures 44-46) and has also been withdrawn with the above claims.

Drawings

The formal replacement drawings were received on 12/23/03. These drawings are approved and were entered into the file. It is noted that the Serial No on these replacement drawings is incorrect (09/542,502). However, these drawings clearly match the previous informal drawings in the file. The typographical error has been corrected by the examiner and dated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20, 27-28, 32-33, 41, 44, 47 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the end" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the periphery" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the end" in line 19. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 recites the limitation "the end" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "the inner surface" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "the portion" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "the inner surface" in line 9. There is insufficient antecedent basis for this limitation in the claim.

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Claim 32 recites the limitation "the portion" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "the end" in line 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "the wall" in line 23 and 24. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the inner surface" in line 9 and 24. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the portion" in line 11, 20 and 24. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the proximal end" in line 13, 17, 26, 31 and 34. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the wall" in line 15, 16, 28 and 30. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the end" in line 18 and 32. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "said proximal end" in line 2. There is insufficient antecedent basis for this limitation in the claim.

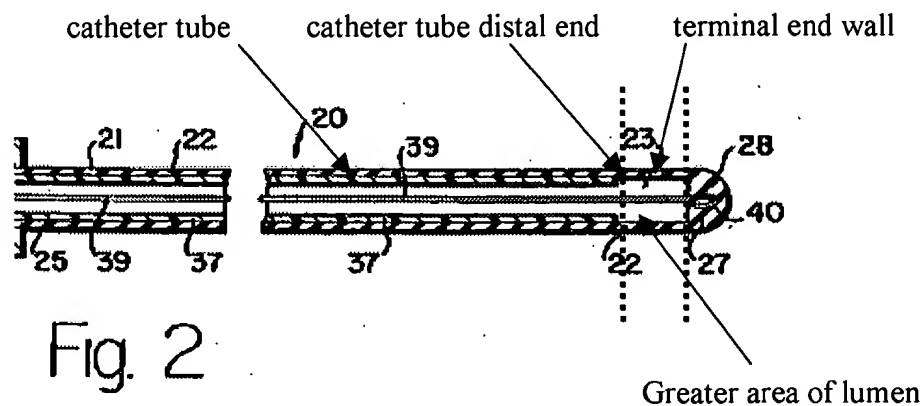
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

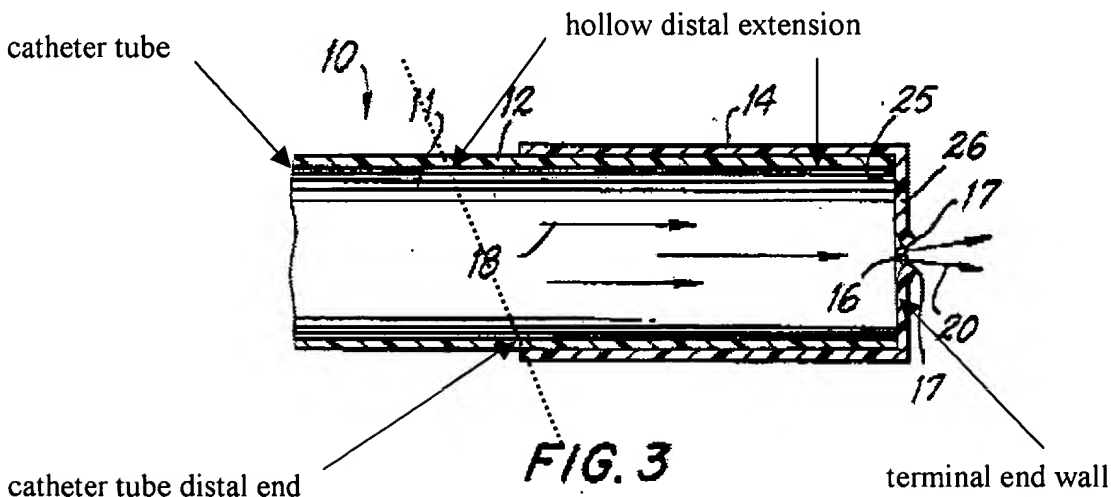
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Alchas (US Pat# 4,737,152). Alchas discloses a catheter assembly that includes a fluid conduit (20) and a slit (29). The fluid conduit further includes a flexible catheter tube (proximal portion of 21) and a terminal end wall (distal portion of 21/22). The catheter tube has an outer wall, a proximal end, a distal end (see below) and a lumen extending therebetween defined by a smoothly continuous inner surface. See figure 2 copied below. The terminal endwall is supported adjacent the smoothly continuous inner surface by the distal end of the catheter tube. See fig 2 below. The cross section is circular. See figures 3-4. The thickness of the terminal end wall is uniform. See fig 2 below. The area of the lumen within the terminal end wall is greater than the area of the lumen in the catheter tube. See fig 2 below.



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Claims 1, 6, 10, 16-22, 41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Alchas (US Pat# 5,030,210). Alchas discloses a catheter valve assembly that includes a fluid conduit (10) and a slit (16). The fluid conduit further includes a flexible catheter tube (proximal portion of 12) and a terminal end wall (26). See figure 3 copied below. The catheter tube has an outer wall, a proximal end, a distal end (see below) and a lumen extending therebetween defined by a smoothly continuous inner surface. See figures 1-6. The terminal endwall is secured directly to and supported adjacent the smoothly continuous inner surface by the distal end of the catheter tube. The cross section is circular. See figures 2,4,6. The thickness of the terminal end wall is uniform. See figures 1,3,5. The intersection of the periphery of the terminal endwall with the outer wall of the distal extension defines a plane of the terminal endwall and the plane of the terminal endwall forms an acute orientation angle with the longitudinal axis of the distal extension. See fig 3 below. The slit acts as a bi-directional valve that (i) closes the fluid passageway (see fig 1), (ii) allows for fluid flow infusion out in a direction aligned with the longitudinal axis of the distal extension (see figure 3), and (iii) allows for aspiration into the passageway (see figure 5).

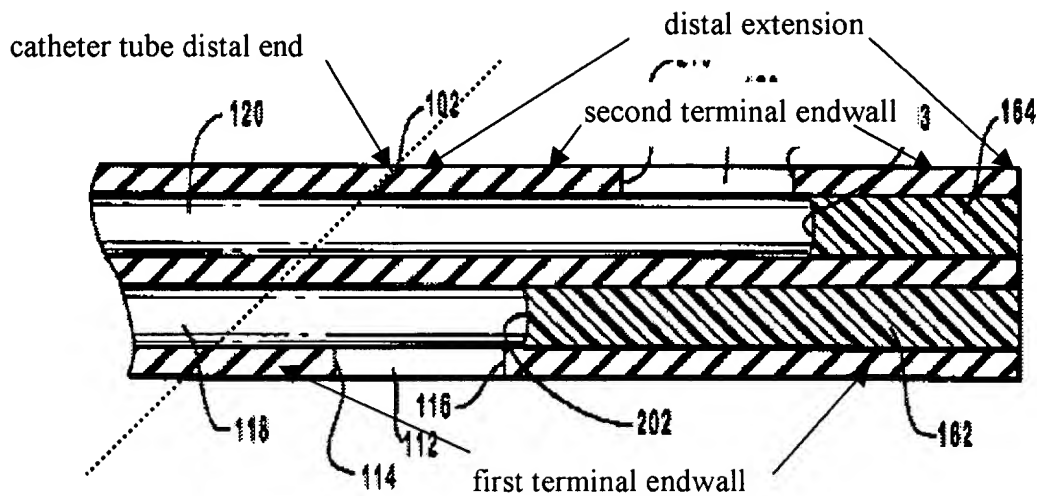


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Claims 1, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hohn (US Pat# 5,147,318). Hohn discloses a valved arterial catheter that includes a fluid conduit (10) and a slit (30). The fluid conduit further includes a flexible catheter tube (10) and a terminal end wall (16). The catheter tube has an outer wall, a proximal end, a distal end (24) and a lumen (12) extending therebetween defined by a smoothly continuous inner surface. See figure 2. The terminal endwall is supported adjacent (22) the smoothly continuous inner surface by the distal end of the catheter tube. See fig 2. The cross section is circular. See figure 3. The area of the lumen (26) within the terminal end wall is greater then the area of the lumen in the catheter tube. See fig 2.

Claims 1, 9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lui (US Pat# 5,304,155). Lui discloses a valved catheter that includes a fluid conduit (11) and a slit (12). The fluid conduit further includes a flexible catheter tube (11) and a terminal end wall (21). The catheter tube has an outer wall, a proximal end, a distal end and a lumen extending therebetween defined by a smoothly continuous inner surface. See figure 4. The terminal endwall is supported adjacent (22) the smoothly continuous inner surface by the distal end of the catheter tube. See fig 4. The terminal endwall is inclined (30) relative to the longitudinal axis of the distal end of the catheter tube. See fig 3 and 4. The thickness of the terminal end wall is less than the thickness of the outer wall of the catheter tube. See figure 4.

Claims 1, 6, 10, 16-18, 21-22, 27-28, 32-33, 41, 47 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al (US Pat# 5,810,789). Powers discloses a fluid conduit and a slit. See figure 16E copied below.

**FIG. 16E**

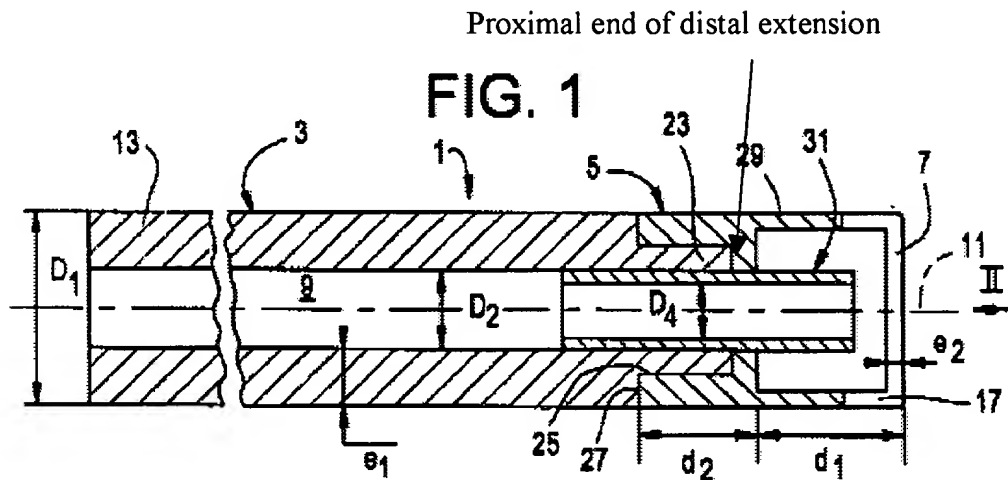
The catheter includes a flexible catheter tube having a proximal end, an open distal end, and a first lumen (118) and a second lumen (120) on opposite sides of an internal septum. The catheter also includes a distal extension that includes an outer wall, an interior wall, first and second fluid passageways, and first and second terminal endwalls, with first and second slits (112,178) respectively. See above.

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 8, 15, 16-17, 21-22 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Nadal (US Pat# 5984903). Nadal discloses a catheter having a valve with a bi-

directional axial slit that includes a catheter tube (3) and a distal extension (5). The distal extension includes an outer wall, a fluid passageway, a terminal end wall (17), a proximal end (see below) and a slit (7). See figure 1.



Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat# 5,843,050 discloses an invention analogous in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *(CSW)*.
March 19, 2004


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